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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/694,569	10/27/2003	Stefan Henke	01-1405	3543

28515 7590 08/01/2011

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EXAMINER	
PURDY, KYLE A	

ART UNIT	PAPER NUMBER
1611	

NOTIFICATION DATE	DELIVERY MODE
08/01/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

USPTO.e-Office.rdg@boehringer-ingelheim.com

Office Action Summary	Application No.	Applicant(s)	
	10/694,569	HENKE ET AL.	
	Examiner	Art Unit	
	K P	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 June 2011*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24 and 26-32* is/are pending in the application.

4a) Of the above claim(s) *21-24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20 and 26-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2 pages (5/25/2011)*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application

1. The Examiner acknowledges receipt of the arguments filed on 6/24/2011 wherein claim 1 has been amended.

2. Claims 1-20 and 26-32 are presented for examination on the merits. The following rejections are made.

Response to Applicants' Arguments

3. Applicants arguments filed 6/24/2011 regarding the rejection of claims 1-8, 13-19, 25 and 27-29 made by the Examiner under 35 USC 103(a) over Ohki et al. (US 2002/0187187) in view of Bock et al. (US 6869948), evidenced by Kosmix have been fully considered and they are found persuasive. The rejection has been overcome by Applicants arguments. Specifically, Applicants have perfected foreign priority by providing a certified translation of the foreign priority document which precludes Ohki from being 35 USC 102 (a) or (b) art. Applicants then submit that Ohki does not qualify as 102(e) as the Ohki reference and the instant application are commonly owned. Applicants 103(c) exemption is sufficient to overcome the Ohki reference to US 2002/0187187.

4. Applicants arguments filed 11/9/2010 regarding the rejection of claim 20 made by the Examiner under 35 USC 103(a) over Skinhoj et al. (US 6599529) in view of Bock et al. (US 6869948), Ouali et al. (US 6183779) and Robinson et al. (US 6071539) have been fully considered. This rejection has been withdrawn in view of a new rejection.

New Rejections
Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. **Claims 1-19 and 26-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Struengmann et al. (US 6284269; published 9/4/2001) in view of Bock et al. (US 6869948; filed 3/26/1999, of record) and Robinson et al. (US 6071539; published 6/6/2000, of record).**

8. Struengmann is directed to fast disintegrating meloxicam formulations. Example V/9 teaches a tablet (with total weight of 3142 mg) comprising meloxicam (58 mg), lactose (1102 mg) (water soluble carrier), polyvinylpyrrolidone (37.7 mg) (water soluble binder), citric acid (942.5 mg) (water soluble carrier), sodium hydrogen carbonate (333.5 mg) (water soluble carrier), sodium sulfate (348 mg) (water soluble carrier), saccharin (8.7 mg) (sweetener), aspartame (58 mg) (sweetener) and flavoring agents. The total weight percent of meloxicam is

about 1.8% by weight, the carrier is present in the formulation is about 87% by weight, the sweetener is present in an amount of about 2.4% by weight and the binder is present in an amount of about 1.2% by weight (math not shown: designations above used). It's noted that Example V/9 includes polydimethylsiloxane which is hydrophilic yet insoluble, however as it is present in an amount of 0.4% by weight which would be expected to not impact the water solubility of the formulation.

9. Struengmann fails to teach the meloxicam as being present as a meglumine salt. Struengmann also fails to teach the flavorant as being selected from the group consisting of vanilla, honey, apple or contramarum.

10. Bock is directed to oral meloxicam compositions. Granular formulations are disclosed in Examples 6 and 7. It is taught that the meloxicam may be a sodium or megluine salt (see claim 1) in order to improve drug (meloxicam) solubility. The ratio between meglumine and meloxicam is taught to be from 1.2:1 to 1:1.2 (see instant claims 18 and 19).The concentration of meloxicam in the granules is about 2% (see Example 6) and 3.5% by weight (see Example 7; see instant claim 17). Moreover, Bock teaches employing the carrier agent(s) (lactose and microcrystalline cellulose) in an amount of about 91% (see Example 6) and 72% (see Example 7). Thus, while Struengmann teaches tablets as carriers for meloxicam, one would have envisaged granules as well as a suitable means for providing analgesic relief to a user in need thereof. Moreover, one would have been motivated to employ meglumine as its presence greatly enhances water solubility of the meloxicam.

11. Robinson is directed to effervescent granules. The granules may be used to provide analgesic relief to a user thereof. The granules are to comprise taste-masking agents such as

sweeteners like aspartame. Table 3 provides a tablet formed from granular particles. The granular particles comprise 5% by weight of aspartame (sweetener) (see column 20, lines 30-40). Flavorants included may be either vanilla or apple.

12. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the formulation of Struengmann with the meglumine of Bock and the apple and/or vanilla flavorant of Robinson a reasonable expectation for success in arriving at a water soluble meloxicam granule comprising meloxicam, a salt forming agent such as meglumine, a binder, a sugar, a carrier and optionally flavorants and other excipients. With respect to the recitation by Applicant that the 5 grams of the instant granules dissolve in 100 mL in demineralized water in about 1 minute to form a clear solution, this would be a property of the obvious composition. As the obvious formulation comprises meloxicam, a salt, a binder, a sugar and a carrier as is instantly claimed, it would be expected to have the properties as instantly claimed, absent evidence to the contrary. With respect to the amounts of binder, sweetener and carrier present in the invention, these are obvious as well. Struengmann teaches including a binder in an amount of about 1.2% and a carrier in an amount of 87% by weight and Robinson teaches providing a sweetener (aspartame) in an amount of 5% by weight. While the binder concentration is less than 2%, Applicants use of "about 2 to about 8 percent" encompasses values reasonably below 2%. Thus, 1.2% is obvious over "about 2%" as an ordinarily skilled person would reasonably recognize that 1.2 is encompassed in the relative amount of about 2%. Therefore, a water soluble granule comprising meloxicam, a salt forming agent, a binder, a carrier, a sweetener and an optional flavorant is *prima facie* obvious to one of ordinary skill in

the art at the time the invention was made, as evidenced by the references, especially in absence of evidence to the contrary.

13. With respect to claims 27-30, Applicant has failed to define what compounds materially affect the basic and novel characteristics of the claimed invention. As Applicant has failed to provide a clear indication for 'consisting essentially of', 'consisting essentially of' will be construed as equivalent to 'comprising', and thus are included in the above rejection. See MPEP 2111.03.

14. **Claims 20 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Struengmann et al. (US 6284269; published 9/4/2001) in view of Bock et al. (US 6869948; filed 3/26/1999, of record) and Ouali).**

15. Struengmann and Bock are discussed in detail above. Briefly, they together teach a composition comprising meglumine, meloxicam and soluble povidone.

16. Struengmann and Bock fail to teach a composition comprising (and consisting essentially) of meloxicam, meglumine, hydroxypropylmethylcellulose (HPMC), soluble povidone and glucose monohydrate.

17. Ouali is directed to stabilizer pharmaceutical composition of a NSAID and a prostaglandin. The composition may be in the form of a granule. The NSAID containing area is to comprise various excipients such as binders and fillers/carriers. Exemplified binders include, but are not limited to, starch (including corn starch and pregelatinized starch), gelatin, sugars (including sucrose, glucose, dextrose and lactose), polyethylene glycol, waxes, and natural and synthetic gums, e.g., acacia sodium alginate, polyvinylpyrrolidone, cellulosic polymers

(including hydroxypropyl cellulose, hydroxypropyl methylcellulose, methyl cellulose, hydroxyethyl cellulose, and the like), and Veegum. Exemplified carriers/fillers include, for example, insoluble materials such as silicon dioxide, titanium oxide, alumina, talc, kaolin, powdered cellulose, microcrystalline cellulose, and the like, as well as soluble materials such as mannitol, urea, sucrose, lactose, dextrose, sodium chloride, sorbitol, and the like (see column 5, line 50 to column 6, line 10). Thus, as it is known that glucose and HPMC are known binders, it would be obvious to employ them in the granule of Struengmann and Bock with a reasonable expectation in imparting suitable binding and/or carrier benefit to the granule formulation.

18. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the formulation of Struengmann with the meglumine of Bock and excipients such as glucose and HPMC as taught by Robinson with a reasonable expectation for success in arriving at a water soluble granule comprising meloxicam, meglumine, HPMC, povidone and glucose. While Ouali fails to teach the glucose as being present as glucose monohydrate, it's well known (common knowledge) that glucose is generally in the form of a monohydrate. With respect to the combining HPMC and glucose of Ouali with dosage form of Streungmann and Bock, this is obvious. Ouali is cited as a general reference for their teaching of excipients commonly used in the delivery of NSAID actives. Knowing that povidone, HPMC and glucose may be employed as binders in pharmaceutical formulations, it would have been obvious to use them together in a combination to deliver meloxicam with a reasonable expectation for success in providing analgesic benefit to a user thereof. Therefore, the instantly claimed subject matter is *prima facie* obvious to one of ordinary skill in the art at the time the

invention was made, as evidenced by the references, especially in absence of evidence to the contrary.

19. With respect to claim 32, Applicant has failed to define what compounds materially affect the basic and novel characteristics of the claimed invention. As Applicant has failed to provide a clear indication for 'consisting essentially of', 'consisting essentially of' will be construed as equivalent to 'comprising'. See MPEP 2111.03.

Conclusion

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kyle A. Purdy whose telephone number is 571-270-3504. The examiner can normally be reached from 9AM to 5PM.

21. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau, can be reached on 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

22. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/K. Purdy/
Examiner, Art Unit 1611
July 26, 2011

/Allison M. Ford/
Primary Examiner, Art Unit 1653